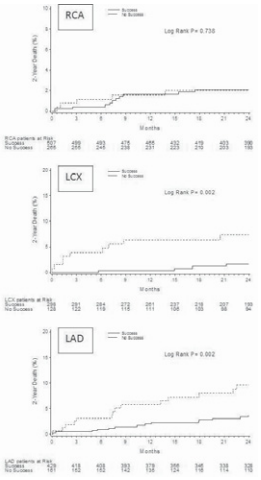

Conclusion: The data from this large contemporary cohort of patients who underwent attempted PCI for CTO's suggest that successful PCI of a CTO in the LAD and the LCX, but not the RCA, is associated with improved long-term survival.

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Drug-Eluting and Bare Metal Stent Studies I

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Wednesday, September 22, 2010, 3:30 pm – 5:30 pm

(Abstract Nos 33-40)

TCT-33

Three-year Follow-up Of The Syntax Trial: Optimal Revascularization Strategy In Patients With Three-vessel Disease

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Background: Many patients (pts) with coronary artery disease present with symptomatic, multivessel disease which leads to poorer revascularization outcomes compared to pts with less complex coronary anatomy. We will present 3 year outcomes of SYNTAX, a novel trial comparing percutaneous coronary intervention (PCI) with TAXUS Express to coronary artery bypass graft surgery (CABG) for pts with *de novo* 3 vessel (3VD) and/or left main (LM) disease.
Methods: SYNTAX is a randomized clinical trial with parallel nested registries. A cardiac surgeon and interventional cardiologist screened consecutive pts with *de novo* 3VD and/or LM disease. Randomization occurred if the patient was amenable to equivalent revascularization using either treatment. Analysis of the 3VD patient cohort was prespecified.
Results: MACCE at 2 years (major adverse cardiac and cerebrovascular events) was significantly higher in the PCI arm (CABG 14.4% vs PCI 23.8%) due, mainly, to increased repeat revascularization (7.5% vs 17.4%) (Table). Death/stroke/MI (8.2% vs 11.1%) and stroke (2.3% vs 1.7%) were similar between groups at 2 years (Table). However, MI (2.8% vs 6.1%, *P*=0.009) and cardiac death (2.3% vs 4.5%, *P*=0.05) were increased in PCI pts (Table). Three year outcomes will be available at the time of the presentation.

Adverse Event Rates at 2 years in the 3VD cohort						
		CABG	PCI		CABG	PCI
2-year Rates	MACCE	14.4	23.8*	Stroke	2.3	1.7
	Death/Stroke/MI	8.2	11.1	MI	2.8	6.1*
	Death	4.1	6.5	Repeat Revascularization	7.5	17.4*

MACCE: All-cause death, stroke, MI, repeat revascularization. Time-to-event rates at 2 years. *$P<0.05$ from log-rank or chi-square test.
Conclusions: This will be the first presentation of 3-year outcomes in the randomized SYNTAX 3VD patient population. Previous results suggest that CABG remains the standard of care for pts with 3VD as CABG-treated pts demonstrated lower MACCE rates compared to PCI at 2 years.

TCT-34

Multivessel Stenting from the RESOLUTE All Comers Open Label Randomized Trial: 12-Month Clinical Outcomes

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Background: The use of drug-eluting stents (DES) has considerably expanded from general use in simple, *de novo*, single lesions, to broader use including multivessel (MV) disease treated with multiple stents. Several randomized clinical trials have compared PCI with early generation DES to coronary artery bypass grafting in patients with MV disease with mixed results. We prospectively planned to evaluate the use of two 2nd generation DES in patients with MV stenting in the controlled, open label, RESOLUTE All Comers non-inferiority trial.
Methods: RESOLUTE All Comers randomized (1:1) 2292 patients to receive the Resolute zotarolimus-eluting stent (R-ZES, Medtronic CardioVascular, Santa Rosa, CA) or the XIENCE-V everolimus-eluting stent (X-EES, Abbott Vascular, Santa Clara, CA). Eligible patients had at least 1 lesion 2.25 _4.0 mm in diameter and a stenosis of > 50%. There were no other lesion or vessel restrictions. The primary composite endpoint at 12 months was target lesion failure, which includes cardiac death, target vessel myocardial infarction, and clinically-driven target lesion revascularization. Multivessel patients were those who had more than 1 vessel treated or attempted with at least 1 stent. Clinical outcomes were compared in 286 R-ZES patients (691 lesions) and 284 X-EES patients (705 lesions).
Results: See Table.

Patient Characteristics

	Resolute ZES* N = 286 patients/691 lesions	Xience V EES* N = 284 patients/705 lesions
Age, yrs	64.4±10.3	64.4±10.7
Male	78.7	77.1
Diabetes	23.8	23.2
Hypertension	71.7	72.2
Hyperlipidemia	64.7	68.7
History of smoking	57.7	57.4
Previous MI	27.1	26.4
Previous PCI	27.6	21.8
Previous CABG	6.3	7.4
ACS	50.0	46.8
Off-label	78.7	76.1
No of treated lesions per patient†	2.42±0.70	2.48±0.77
SYNTAX Score	20.8±9.6	19.5±9.1

*P>0.05 for all comparisons. †Includes index and staged procedures. All data as (%) or mean±SD.

Conclusions: The RESOLUTE All Comers trial will be presented as a late-breaking clinical trial at EuroPCR in May, 2010. The results have also been submitted for publication, therefore are under embargo. We look forward to presenting the results for MV patients from the RESOLUTE All Comers trial at TCT in September, 2010.

TCT-35

A Large-Scale Randomized Comparison of Everolimus-Eluting and Paclitaxel-Eluting Stents: Two-Year Clinical Outcomes from the SPIRIT IV Trial

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Background: In the SPIRIT IV randomized trial, the largest clinical trial to date comparing two drug-eluting stents, the XIENCE V everolimus-eluting stent (EES) compared to the TAXUS EXPRESS2 paclitaxel-eluting stent (PES) resulted in significantly reduced rates of target lesion failure (TLF) and ischemia-driven target lesion revascularization (ID-TLR), with non-inferior rates of composite cardiac death or target-vessel myocardial infarction (MI) at 1 year. Treatment with EES also resulted in a significant reduction in the Academic Research Consortium-defined rate of definite or probable stent thrombosis, and of any MI. Overall outcomes through 2 years have not yet been reported.
Methods: In the SPIRIT IV trial, 3,687 patients were prospectively randomized 2:1 to EES vs. PES. Patients with up to 3 de novo native coronary artery lesions (maximum 2 lesions per epicardial vessel) with length no more than 28 mm and reference vessel diameter >=2.5 mm to <=4.25 mm were enrolled at 66 U.S. clinical sites, stratified by diabetes and lesion complexity. Routine angiographic follow-up was not performed. The trial was powered to demonstrate sequential noninferiority and superiority of EES compared to PES for the primary composite endpoint of TLF at 1 year, consisting of cardiac death, target vessel MI, or ID-TLR.
Results: One-year follow-up results have been presented, and 2-year results for all patients will be available in August 2010. In addition to the overall cohort, results through 2 years will also be reported in the large subset of patients with diabetes mellitus (1185 randomized patients), in whom TLF rates between EES and PES were not significantly different.
Conclusions: The two-year outcomes from the SPIRIT IV randomized trial will provide important insights into the long-term safety and efficacy of these 2 stent platforms.